

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: David LEWIS, et al.

GAU:

SERIAL NO: New Application

EXAMINER:

FILED: Herewith

FOR: PHARMACEUTICAL AEROSOL COMPOSITION

REQUEST FOR PRIORITY

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

☒ Full benefit of the filing date of U.S. Application Serial Number 10/435,354, filed May 12, 2003; U.S. Application Serial Number 09/796,607, filed March 2, 2001; U.S. Application Serial Number 09/147,669, filed February 24, 1999; and International Application No. PCT/EP98/03533, filed June 10, 1998, are claimed pursuant to the provisions of 35 U.S.C. §120.

☐ Full benefit of the filing date(s) of U.S. Provisional Application(s) is claimed pursuant to the provisions of 35 U.S.C. §119(e): Application No. Date Filed

☒ Applicants claim any right to priority from any earlier filed applications to which they may be entitled pursuant to the provisions of 35 U.S.C. §119, as noted below.

In the matter of the above-identified application for patent, notice is hereby given that the applicants claim as priority:

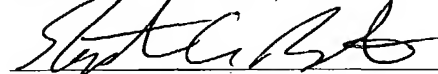
<u>COUNTRY</u>	<u>APPLICATION NUMBER</u>	<u>MONTH/DAY/YEAR</u>
United Kingdom	97 12434.1	June 13, 1997
WIPO	PCT/EP98/03533	June 10, 1998

Certified copies of the corresponding Convention Application(s)

- ☐ are submitted herewith
- ☐ will be submitted prior to payment of the Final Fee
- ☐ were filed in prior application Serial No. filed
- ☒ were submitted to the International Bureau in PCT Application Number PCT/EP98/03533, filed June 10, 1998.
- ☐ (A) Application Serial No.(s) were filed in prior application Serial No. filed ; and
- ☐ (B) Application Serial No.(s)
 - ☐ are submitted herewith
 - ☐ will be submitted prior to payment of the Final Fee

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.


Stephen G. Baxter, Ph.D.

Registration No. 32,884



22850

U.S. Application No.: New Application (Divisional of U.S. Application No. 10/435,354)
37 CFR 1.604 Request for an Interference with an Application

DOCKET NO.: 239770US0 DIV

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

DAVID LEWIS ET AL :

GROUP ART UNIT: UNASSIGNED

SERIAL NO: NEW APPLICATION
(DIVISIONAL OF 10/435,354) :

EXAMINER: UNASSIGNED

FILED: HEREWITH :

FOR: PHARMACEUTICAL AEROSOL COMPOSITION

37 CFR 1.604 REQUEST FOR AN
INTERFERENCE WITH AN APPLICATION

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

I. 37 CFR 1.604(a)(1)

Applicants propose the following count, which is in the format approved by the
Commissioner in Orikasa v. Oonishi, 10 USPQ2d 1999, 2003 (Comm'r 1990), and Davis v. Uke,
27 USPQ2d 1180, 1188 (Comm'r 1993):

Claims 24-45 of the party Lewis et al.'s application filed herewith;

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OR

Claims 1-28 of the party Buenafae et al.'s application serial No. 10/176,851, published as US 2003/0053957 A1 on March 20, 2003.

It should particularly be noted that, pursuant to the Commissioner's opinion in Orikasa, it is appropriate to use a count of this type where the recited claims are in different statutory classes so long as the subject matter recited in the various claims is not patentably distinct.

An extra copy of the proposed count is submitted herewith for the examiner's use in filling out the form PTO-850. In addition, as explained in Section V of this request, a proposed form PTO-850 is submitted herewith for the examiner's convenience.

Claims 24-45 presented in the 37 CFR 1.604(a)(1) amendment submitted herewith correspond to the proposed count. Indeed, the proposed count includes all of the independent claims in that group of claims.

II. 37 CFR 1.604(a)(2)

The other application is application serial No. 10/176,851 filed June 20, 2002, and naming Mina Buenafae et al. as inventors, and published as US 2003/0053957 A1 on March 20, 2003. If that application is now abandoned, this request is directed to any continuation of that application now pending. Buenafae et al.'s application serial No. 10/176,851, is a continuation

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of application serial No. 09/768,915, filed January 24, 2001, now abandoned, and published as
US 2002/0085978 A1 on July 4, 2002.

Applicants believe that all claims in application serial No. 10/176,851 or any continuation
of that application now pending correspond to the proposed count. However, since applicants do
not have access to that application, they cannot be sure.

III. 37 CFR 1.604(a)(3)

The interference should be declared because, as shown by the table below, the parties are
claiming the same patentable invention.

Buenafae et al. Application
10/176,851

1. A pharmaceutical composition
comprising

a glucocorticosteroid,

a propellant,

a cosolvent, and

a radical quencher.

Lewis et al. Application

24. A pharmaceutical composition
comprising

a corticosteroid,

a propellant,

a cosolvent, and

an antioxidant.

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2. The pharmaceutical composition of claim 1,

wherein the radical quencher is ascorbyl palmitate.

3. The pharmaceutical composition of claim 1,

wherein the radical quencher is Vitamin E.

4. The pharmaceutical composition of claim 1,

wherein the radical quencher is selected from the group consisting of ascorbic acid, ascorbyl palmitate, sodium bisulfite, butylated hydroxytoluene (BHT), butylated [*sic*, butylated] hydroxyanisole (BHA), glutathione, ubiquinone, carotenoids and vitamin E and functional equivalents and/or derivatives thereof.

25. The pharmaceutical composition of claim 24,

wherein said antioxidant is ascorbyl palmitate.

26. The pharmaceutical composition of claim 24,

wherein said antioxidant is tocopherol.

27. The pharmaceutical composition of claim 24,

wherein said antioxidant is selected from the group consisting of ascorbic acid, ascorbyl palmitate, butylated hydroxytoluene, butylated hydroxyanisole, and tocopherol.

5. The pharmaceutical composition of claim 1,

wherein the glucocorticosteroid is selected from the group consisting of budesonide, testosterone, progesterone, estrogen, flunisolide, triamcinolone, eclomethasone, betamethasone, dexamethasone, fluticasone, methylprednisolone, prednisone, hydrocortisone, ciclesonide, mometasone, desonide, and rofleponide.

7. The pharmaceutical composition of claim 1,

wherein the propellant is 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoro-n-propane or a mixture thereof.

9. The pharmaceutical composition of claim 7,

wherein the polyol is a C₂-C₆ alcohol.

10. The pharmaceutical composition of claim 7,

wherein the polyol is selected from the group consisting of ethanol, isopropanol, and propylene glycol.

28. The pharmaceutical composition of claim 24,

wherein the corticosteroid is selected from the group consisting of flunisolide and beclomethasone dipropionate.

29. The pharmaceutical composition of claim 24,

wherein the propellant is 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, or a mixture thereof.

30. The pharmaceutical composition of claim 24,

wherein said cosolvent is an alcohol.

31. The pharmaceutical composition of claim 30,

wherein said alcohol is ethanol.

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11. A pressurized metered dose inhaler comprising

a container equipped with a metering valve and

containing a pressurized aerosol formulation comprising

a glucocorticosteroid,

a propellant,

a cosolvent, and

a radical quencher.

32. A pressurized metered dose inhaler comprising

a container equipped with a metering valve and

containing a pressurized aerosol formulation comprising

a corticosteroid,

a propellant,

a cosolvent, and

an antioxidant.

12. The pressurized metered dose inhaler according to claim 11,

wherein the glucocorticosteroid is selected from the group consisting of budesonide, testosterone, progesterone, estrogen, flunisolide, triamcinolone, beclomethasone, betamethasone, dexamethasone, fluticasone, methylprednisolone, prednisone, hydrocortisone, ciclesonide, mometasone, desonide, and rofleponide.

33. The pressurized metered dose inhaler according to claim 32,

wherein the corticosteroid is selected from the group consisting of flunisolide and beclomethasone dipropionate.

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14. The pressurized metered dose inhaler according to claim 11,

wherein the propellant is 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoro-n-propane or a mixture thereof.

16. The pressurized metered dose inhaler according to claim 15,

wherein the polyol is a C₂-C₆ alcohol.

17. The pressurized metered dose inhaler according to claim 15,

wherein the polyol is selected from the group consisting of ethanol, isopropanol, and propylene glycol.

18. The pressurized metered dose inhaler according to claim 11,

wherein the radical quencher is ascorbyl palmitate.

19. The pressurized metered dose inhaler according to claim 18,

wherein the radical quencher is Vitamin E acetate.

34. The pressurized metered dose inhaler according to claim 32,

wherein said propellant is 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, or a mixture thereof.

35. The pressurized metered dose inhaler according to claim 32,

wherein said cosolvent is an alcohol.

36. The pressurized metered dose inhaler according to claim 35,

wherein said alcohol is ethanol.

37. The pressurized metered dose inhaler according to claim 32,

wherein said antioxidant is ascorbyl palmitate.

38. The pressurized metered dose inhaler according to claim 32,

wherein said antioxidant is tocopherol.

20. A method for the treatment of a bronchial disorder or an inflammatory bowel disorder in a mammal by

administering a pharmaceutical formulation comprising

a glucocorticosteroid,

a propellant,

a cosolvent, and

a radical quencher.

39. A method for the treatment of a bronchial disorder comprising

administering a pharmaceutical formulation comprising

a corticosteroid,

a propellant,

a cosolvent, and

an antioxidant.

21. The method according to claim 20,

wherein the glucocorticosteroid is selected from the group consisting of budesonide, testosterone, progesterone, estrogen, flunisolide, triamcinolone, beclomethasone, betamethasone, dexamethasone, fluticasone, methylprednisolone, prednisone, hydrocortisone, ciclesonide, mometasone, desonide, and rofleponide.

40. The method according to claim 39,

wherein said corticosteroid is selected from the group consisting of flunisolide and beclomethasone dipropionate.

23. The method according to claim 20,

wherein the propellant is 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoro-n-propane or a mixture thereof.

41. The method according to claim 40,

wherein said propellant is 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane or a mixture thereof.

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25. The method according to claim 24,
wherein the polyol is a C₂-C₆ alcohol.

42. The method according to claim 40,
wherein said cosolvent is an alcohol.

26. The method according to claim 24,
wherein the polyol is selected from the
group consisting of ethanol, isopropanol,
and propylene glycol.

43. The method according to claim 42,
wherein said alcohol is ethanol.

27. The method according to claim 20,
wherein the radical quencher is ascorbyl
palmitate.

44. The method according to claim 40,
wherein said antioxidant is ascorbyl
palmitate.

28. The method according to claim 20,
wherein the radical quencher is Vitamin E
acetate.

45. The method according to claim 40,
wherein said antioxidant is tocopherol.

The only differences in the language of Claim 1 of Buenafae et al.'s application serial No. 10/176,851 and Claim 24 of Lewis et al.'s application filed herewith is that Claim 1 of Buenafae et al.'s application recites the presence of a "glucocorticosteroid" and a "radical quencher," while Claim 24 of Lewis et al.'s application recites the presence of a "corticosteroid" and an "antioxidant." However, the glucocorticosteroids of Buenafae et al. are a subset of the corticosteroids of Lewis et al. Moreover, at least two

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of the corticosteroids of Lewis et al., flunisolide and beclomethasone dipropionate, are also glucocorticosteroids as defined by Buenaface et al. In addition, the radical quenchers of Buenaface et al. are the same as the antioxidants of Lewis et al. (see, "Antioxidants," in Kirk-Othmer, Encyclopedia of Chemical Technology, 4th Ed., Wiley, vol. 3, pp. 424-447 (1992).

Thus, it is clear that the parties are claiming the same patentable invention.

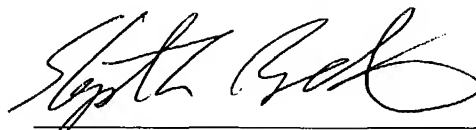
IV. REQUEST FOR THE BENEFIT OF THE FILING DATES OF APPLICANTS' PRIORITY APPLICATIONS

Applicants claim priority under 35 USC 120 based upon U.S. application serial Nos. 10/435,354; 09/796,607; and 09/147,669 and PCT application No. PCT/EP98/03533. The present application is a divisional application of U.S. application serial No. 10/435,354 ("the '354 application") filed May 12, 2003. The '354 application is a continuation of U.S. application serial No. 09/796,607 ("the '607 application") filed March 2, 2001. The '607 application was a continuation application of US application serial No. 09/147,669 ("the '669 application") filed February 24, 1999. The '669 application was a 371 of PCT application No. PCT/EP98/03533 ("the '533 application") filed June 10, 1998. Applicants also claim priority under 35 USC 119 based upon UK application No. 9712434 ("the '434 priority application") filed June 13, 1997.

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Applicants are entitled to the benefit of the filing dates of their earlier filed applications for interference purposes if the count reads on at least one adequately disclosed embodiment in the earlier application.¹ Assuming that the examiner recommends to the board applicants' proposed count, applicants clearly meet that standard.

Respectfully submitted,



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¹Weil v. Fritz, 572 F.2d 856, 865-66 n.16, 196 USPQ 600, 608 n.16 (CCPA 1978).